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APPLICATION NO.	FILING DATE	FIRST-NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,720	12/01/2000	Steven K. H. Foung	2002850-0009	5311

7590 11/18/2003

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EXAMINER

WORTMAN, DONNA C

ART UNIT PAPER NUMBER

1648

DATE MAILED: 11/18/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/728,720

Applicant(s)

FOUNG ET AL.

Examiner

Donna C. Wortman, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,8,9,12,14-22,25-28,92,93,95,97,103-107 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9,92,93,95,97 and 103-107 is/are allowed.
- 6) ☒ Claim(s) 1,8,12,14,15,17-19,22,25,26 and 28 is/are rejected.
- 7) ☒ Claim(s) 16,20,21 and 27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 September 2003 has been entered.

Claims 1, 8, 9, 12, 14, 25-27, 92, 93 and 105 were amended, claims 4-7, 10, 11, 13, 23, 29-32, 67, 70, 75-91, 96 and 98-102 were canceled, and claims 106 and 107 were added in Paper No. 22 filed 17 September 2003. An amendment to the specification at page 6 has been entered as requested in Paper No. 22. Claims 1, 8, 9, 12, 14-22, 25-28, 92, 93, 95, 97, 103-105, 106 and 107 are pending and under examination.

The terminal disclaimer filed on 17 September 2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of Patent Application Serial No. 09/430489 has been reviewed and is accepted. The terminal disclaimer has been recorded.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 8, 12, 14, 15, 17, 18, 19, 22, 25, 26, and 28 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Persson et al. Persson et al. disclose anti-HCV E2 human antibodies derived from combinatorial libraries, as well as nucleic acids encoding them; vectors; host cells and cell lines for expressing the vectors, and methods of making more antibodies *in vivo* and *in vitro*. See, e.g., pages 40-43 and Examples 4-12. The antibodies and cell lines of Persson et al. reasonably appear to be the same as, or only slightly different from, the claimed antibody CBH-2 and cell lines for expressing it, since the prior art antibodies were obtained from HCV infected individuals, they were selected in the same manner, they bind to conformational epitopes on the HCV E2 protein, and they give the same or

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similar results in neutralization of binding assays; thus, in the absence of factual evidence to the contrary, they reasonably appear to be the same as or only slightly different from the antibodies and cell lines of claims 1, 8, 12, 14, 15, 17, 18, 19, 22, 25, 26, and 28, insofar as the claims are drawn to the antibody designated as CBH-2.

Applicant has submitted a Declaration under 37 CFR 1.132 from Dr. Fount demonstrating that claimed antibodies are structurally different from the prior art antibodies.

The Declaration and Applicant's remarks have been considered but not found entirely persuasive. In particular, the comparisons presented in Exhibit D are not commensurate in scope with the claims because there is no comparison of the amino acid sequences that determine antigen binding specificity for antibody CBH-2 with the prior art antibody sequences. In the absence of such comparison or other factual evidence, the assertion that antibody CBH-2 does not bind to the same epitope as one or more of the Persson antibodies relies on arguments not supported by facts and is not persuasive.

Claims 16, 20, 21, and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Persson et al. do not disclose or suggest the use of a B cell line as recited in claim 16, nor the use of a hybridoma cell line as recited in claim 20, nor the use of a cell line transformed with Epstein Barr virus as recited in claim 21, for expressing anti-HCV E2 antibodies selected from a

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combinatorial library. Persson et al. do not teach or suggest making a humanized antibody as recited in claim 27.

Claims 9, 92, 93, 95, 97, 103, 104, 105, 106, and 107 are allowed. The Declaration of Dr. Fong has been considered and found persuasive in demonstrating that claimed antibodies CBH-4G, CBH-5, CBH-7, CBH-8C, and CBH-11 are not the same as, and do not bind the same epitopes as, antibodies taught by Persson et al. in WO 97/40176.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw,